REMARKS/ARGUMENTS

In response to the Office Action mailed June 28, 2005, Applicants amend their application and request reconsideration in view of the amendments and following remarks. In this amendment, Claim 1 is amended, claims 4 – 8 have been cancelled without prejudice and no claims have been added so that Claims 1-3, 16 and 17 are currently pending. No new matter has been introduced.

Claims 1 – 8, 16 and 17 were rejected under 35 U.S.C. § 112, first paragraph. Applicants have amended the claims to overcome this rejection. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-3, 6 and 17 were rejected as being anticipated by U.S. Patent No. 5,833,651 to Donovan et al. (Donovan). This rejection is respectfully traversed.

Donovan discloses a stent having a polymeric composition affixed thereto. The polymeric composition comprises fibrin. The stent also comprises a virus associated with the polymeric coating. In some embodiments, a powder form of heparin may be affixed to the stent during the polymerization process and additional thrombin and fibrinogen can then be applied on a coating over the heparin.

Anticipation exists only if all of the elements of the claimed invention are present in a system or method disclosed, expressly or inherently, in a single prior art reference. Therefore, if it can be shown that there is one difference between the claimed invention and what is disclosed in the single reference, there can be no anticipation.

The present invention as claimed in independent Claim 1 is direct to a local drug delivery apparatus. The apparatus comprises a medical device, a polymeric coating including a rapamycin and a biocompatible, water-soluble powder applied to a surface of the polymeric material configured to prevent the layer affixed to the medical device from separating.

Donovan fails to disclose or suggest a polymeric matrix comprising a rapamycin. Donovan fails to disclose or suggest a surface treatment of a water soluble powder. What Donovan does teach is adding a heparin powder during the polymerization process and then covering it with other material; namely, thrombin and fibromogen. Since not all the elements of the claimed invention are not taught, there can be no anticipation. Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

Claims 1-8 and 17 were rejected as being unpatentable over U.S. Patent Application Number 2002/0041899 to Chudzik et al. (Chudzik) in view of Donovan. This rejection is respectfully traversed.

Chudzik discloses a coating composition for use in delivering a medicament from the surface of a medical device positioned *in vivo*. Medicaments include a wide range of biologically active materials or drugs. A wide range of drugs and/or agents are set forth in the disclosure. Medical devices include a wide range of implantable and removable devices such as vascular stents and grafts. The medicament is typically incorporated into a polymeric matrix after the matrix itself has been coated onto a medical device. Essentially, the medical device is soaked in a medicament solution wherein it is absorbed into the matrix and the device is air dried. In certain embodiments, another polymer layer comprising the same or different polymer than that of the base layer can be affixed to the device. The medicament layer can pass through this topcoat. This method of using the second polymer layer allows for a more lubricious device according to the disclosure.

Paragraph [0080] of Chudzik sets forth the how and why of utilizing an additional coating.

[0080] If desired, for instance, such an additional coating can be applied on top of a medicament absorbing layer, either before and/or after medicament has been

absorbed into the matrix. It is preferable to add the additional layer before medicament has been absorbed. For instance, a solution of the same or of a different copolymer can be prepared and the coated device dipped, sprayed or otherwise contacted with the solution and illuminated as described previously. The coated device can then to contacted with, e.g., soaked in, the medicament solution as described previously. Medicament will pass through the top coat and be absorbed by the underlying matrix. When placed in the body, the medicament will be released as described herein. Using such a method, a coating with enhanced lubricity, hemocompatibility, or other desired property can be incorporated into the medical device surface, thus forming a device coating that provides multiple desired properties.

The present invention, as claimed in amended independent Claim 1, is directed to a local drug delivery device which comprises a medical device for implantation into a treatment site of a living organism, a layer including a rapamycin, in therapeutic dosages, incorporated in a polymeric matrix and affixed to the medical device for the treatment of reaction by the living organism caused by the medical device or the implantation thereof, and a biocompatabile water soluble powder configured to prevent the at least one agent from separating from the medical device prior to implantation. The biocompatabile water-soluble powder being applied to the surface of the layer affixed to the medical device.

The MPEP, in section 706.02(j), sets forth the basic criteria that must be met in order to establish a *prima facie* case of obviousness.

> "To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references

> when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d,488,20 USPQ2d 1438 (Fed.Cir. 1991). See MPEP § 2143 - § 2143.03 for decisions pertinent to each of these criteria."

Section 2143.03 of the MPEP clarifies certain criteria in section 706.02(j).

> "To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1074). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)."

It is respectfully submitted that Chudzik fails to teach or suggest all of the claimed limitations. Chudzik does teach the coating of a medical device with a polymeric coating containing a medicament. Chudzik also teaches the use of an additional layer. Chudzik goes on to teach that a solution of the same or a different copolymer can be prepared and then the coated device may be dipped, sprayed or otherwise contacted with the solution. Essentially, Chudzik teaches the use of a solution of polymer or copolymer that may be affixed to the already coated device, regardless of the method of delivery of the solution.

Neither Donovan nor Chudzik, whether taken alone or in combination, however, do not disclose a medical device coated with a polymeric matrix containing a rapamycin and a bio-compatable water soluble powder applied to the surface of the polymeric layer. The biocompatabile water-soluble powder is not a solution of polymer or copolymer.

In making the rejection, the Examiner contends that a water-soluble powder is within the scope of paragraph [0080] of Chudzik and it would have been obvious to one with ordinary skill in the art to have the lubricant be a water-soluble powder. Applicants respectfully disagree. As was held in In re Gordon, 733 F.2d 900, 902, 221 USPQ 1125,1129 (Fed.Cir. 1984), "The mere fact that the prior art could be so modified would not have made the modification obvious unless the prior art suggested the desirability of the modification." There is simply no suggestion in Chudzik that would lead one of ordinary skill in the art to substitute a non-polymeric water-soluble powder for a polymeric solution.

The Examiner further contends that the specification does not demonstrate the criticality of a "powder" nor any example of such a powder. It is respectfully submitted that criticality is not a factor in patentability. In W.L. Gore & Assoc. v. Garluck, Inc., 721 F.2d 1540, 1536, 220 USPQ 300,315 (Fed.Cir. 1983), cert. demied 469 U.S. 851 (1984), the court held that a claim to a new product is not legally required to include critical limitations. See also Ex Parte Patrick J. Allen et al., Appeal No. 97-2597, heard July 16, 1999 before the Board of Patent Appeals and Interferences.

In addition, Applicants disagree with the characterization that no examples of water-soluble powders are given. The specification from line 31 on page 26 to line 20 on page 31 sets forth the type of powder, the reason for its use and examples, such as vitamin C and aspirin.

Finally, the powdered form of heparin is added during the polymerization process and covered with thrombin and fibromogen. Clearly, this is not configured to

prevent the elements from sticking to themselves as claimed in the present invention. Once the powder is added to the polymer solution it is not serving its protective function, but rather a therapeutic function.

For the reasons given above, Applicant's respectfully request reconsideration and withdrawal of the rejection.

A favorable response is respectfully requested.

Respectfully submitted,

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